

### REMARKS

This paper is filed in response to the Office Action mailed on July 18, 2005.

No claims have been cancelled. Minor clarification amendments have been made to independent claims 1, 11 and 19-20 and typographical errors in claims 3 and 5 have been corrected. Support for all claim amendment appears in the SUMMARY OF THE DISCLOSURE section of the application and Figs. 10-11 of the application as filed. No new matter is added thereby. Claims 1-20 remain pending.

The Office objects to applicant's use of the term "fixedly," claiming fixedly is not a word. However, fixedly is a word. It appears on page 468 of *Webster's Ninth New Collegiate Dictionary* (1983) as an adverb form of the adjective "fixed." Further, a word search on the USPTO website for patents using the term "fixedly" in a US patent reveals 192,540 US patents with the term fixedly "anywhere" in the patent and 71,558 US patents with the term "fixedly" used in the claims. For both searches, the "Quick Search" function was utilized. Therefore, the Office's objection to this applicant's use of the term fixedly is traversed.

Next, the Office objects to applicant's use of the heading SUMMARY OF THE DISCLOSURE instead of the conventional SUMMARY OF THE INVENTION. However, there is no *requirement* in the MPEP or 37 CFR that SUMMARY OF THE INVENTION be used as opposed to SUMMARY OF THE DISCLOSURE. Further, 37 CFR §1.73 and MPEP §608.01(d) repeatedly use the term "should" when discussing the "Brief Summary" section of an application. Thus, the "Brief Summary" section is clearly optional and the naming or title of the section remains the option of applicant. Applicant has the right to present her application as she sees fit, so long as her application is within the confines of the CFR. Applicant's use of SUMMARY OF THE DISCLOSURE is not in violation of any rule and the therefore the Office's objection to this heading is traversed.

The Office rejects claims 5-9 under 35 USC §112, 2<sup>nd</sup> ¶ as allegedly being indefinite. In response, claim 5 has been amended to make it dependent from claim 3 thereby traversing this rejection.

Turning to the rejections based on the prior art, the Office has rejected every claim as allegedly being anticipated by U.S. Patent No. 5,634,928 ("Fischell"). However, applicant respectfully submits that this rejection fails to meet the standard of MPEP § 2131, which recites:

[t]o anticipate a claim, the reference must teach every element of the claim.  
"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

*Citing, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As shown below, Fischell fails to include every element of each pending independent claim and therefore the anticipation rejection of claims 1-20 is improper and must be withdrawn.

In its rejection, the Office states that the Fischell tube 13 is the equivalent of the claimed "inner shaft." The Office then equates the Fischell tube 24 with the claims "outer shaft" and the Fischell member 11 with the claimed "rigid inner member."

However, each independent claim requires the inner rigid member to be "fixedly connected to" the inner shaft. This structural relationship enables fixed relationship between the catheter 100, the rigid inner member 20 and the inner shaft 18 which in turn enables the outer shaft 16 to be retracted with respect to the inner shaft 18 and catheter 100 (see Figs. 10-11). Retraction of the outer shaft 16 results in retraction of the outer sheath 96 with respect to the catheter 100 which is held in place by the fixed relationship between the inner shaft 18, inner member 20 and catheter 100.

Fischell fails to disclose this relationship. First, the Fischell tube 13 is not fixedly connected to the Fischell tube 11 as alleged by the Office. Instead, the Fischell tube 13 is connected to the balloon 16, which in turn is connected to the member 11. The balloon 16 is inflatable and therefore stretchable by its very nature. The elastic, stretchable connection the balloon 16 provides between the Fischell tube 13 and tube 11 is not a fixed connection (or is not fixedly connected) as recited in each independent claim because fixedly means "securely placed or fastened: STATIONARY," *Webster's Ninth New Collegiate Dictionary*, p. 468 (1983).

Further, the Fischell inner tube 11, which the Office equates with the claimed rigid inner member, is highly flexible at its distal end:

FIG. 1 shows that the inner tube 11 has a distal portion 11A that extends for a considerable distance beyond the distal end of the balloon 16. Also the distal portion 11A has a distal end 11B that has a conical taper. Because of the conical shape of the distal end 11B and *because the distal portion 11A of the inner tube 11 is highly flexible*, the integrated catheter 10 can readily track over a highly flexible guide wire 30. *The distal end of the balloon 19 is adhesively joined to the proximal end of the distal portion 11A of the inner tube 11. The proximal end of the balloon 16 is adhesively joined to the distal end of the outer tube 13.* See col. 4, lines 7-17 (emphasis added).

Thus, Fischell does not teach or suggest an inner rigid member that is fixedly connected to an inner tube as required by each independent claim. The Fischell inner tube 11 is not rigid as recited by each independent claim and the Fischell tube 13 is not fixedly connected to the tube 13. Instead, the tube 13 is connected to a balloon 16 and a luer fitting 50 (see Figs. 1 and 3).

Fischell also fails to teach or suggest the relationship between the inner and outer shafts as recited in the pending independent claims. Each claim requires the inner shaft to have distal end that is disposed proximally to the distal end of the outer shaft in the first position. Fischell does not teach this relationship. Instead, the inner tube 13 of Fischell has a distal end that is *always* disposed distally with respect to the distal end of the tube 24. See Fig. 1 of Fischell. Thus, for this additional reason, the anticipation rejection of claims 1-20 must be withdrawn.

Finally, Fischell teaches nothing about the use of an inner shaft disposed within an outer shaft and the use of that outer shaft to retract a sheath. Fischell only teaches the use of a pusher tube 24, not a retraction tube. The Fischell device is not capable of retraction and no modification of the Fischell device would render it useful for retracting a sheath from a stent. Essentially, Fischell is irrelevant to the problem of safely retracting a sheath from a stent during an intravascular procedure.

The anticipation rejection does not meet the standard of MPEP § 2131, is improper and must be withdrawn.

A new power of attorney and revocation of prior powers has been filed.

An early action indicating the allowability of this application is earnestly solicited.

The Patent Office is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-3629.

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Respectfully submitted,

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